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Application of: Buchman et al.

Serial No.: 09/524,101

Filed: March 13, 2000

For: Insect p53 Tumor Suppressor
Genes and Proteins

Group Art Unit: 1655

Examiner: Taylor, Janell E.

Attorney Docket No: EX00-015C

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir: -

This is responsive to the office action mailed November 28, 2001. No fees are believed to be due at this time. However, if this belief is in error, the Commissioner is authorized to charge any required fees to deposit account no. 50-1108.

Amendment

Amendment to specification

On page 17, replace the paragraph on lines 20-21, with the following paragraph:

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Other preferred p53 polypeptides, fragments or derivatives consist of or comprise a sequence selected from the group consisting of RICSCP KRD (SEQ ID NO:23), KICSCP KRD (SEQ ID NO:24), RVCSCP KRD (SEQ ID NO:25), KVCSCP KRD (SEQ ID NO:26), RICTCP KRD (SEQ ID NO:27), KICTCP KRD (SEQ ID NO:28), RVCTCP KRD (SEQ ID NO:29), and KVCTCP KRD (SEQ ID NO:30) (i.e. sequences of the formula: (R or K)(I or V)C(S or T)CP KRD). Additional preferred p53 polypeptides, fragments or derivatives, consist of or comprise a sequence selected from the group consisting of FXCKNSC (SEQ ID NO:31) and FXCQNSC (SEQ ID NO:32), where X = any amino acid.

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The amendment adds Seq ID Nos. 23-32. A replacement sequence listing is filed herewith. A marked-up version of the replacement paragraph is provided in Appendix B, where underlining denotes newly added text

Amendment to claims

Please amend the claims as follows:

2. (Amended) The isolated nucleic acid molecule of Claim [1] 4 that is RNA.

3. (Amended) The isolated nucleic acid molecule of Claim 4 [1 wherein the nucleic acid sequence has at least 50% sequence identity with] that hybridizes under stringent hybridization conditions with a nucleic acid having a sequence selected from the group consisting of any of SEQ ID NOs:1, 3, 5, 7, 9, and 18[, 19 and 21].

4. (Amended) [The] An isolated nucleic acid molecule that encodes a polypeptide selected from the group consisting of an insect p53 polypeptide, a dominant negative form of said insect p53 polypeptide, a constitutively active form of said insect p53 polypeptide, and a domain of said insect p53 polypeptide selected from the group consisting of an activation domain, a DNA binding domain, a linker domain, an oligomerization domain, and a basic regulatory domain; wherein said insect p53 polypeptide comprises [of Claim 1 wherein the nucleic acid sequence encodes a polypeptide comprising] an amino acid sequence selected from the group consisting of: RICSCPGRD (SEQ ID NO:23), KICSCPGRD (SEQ ID NO:24), RVCSCPGRD (SEQ ID NO:25), KVCSCPGRD (SEQ ID NO:26), RICTCPGRD (SEQ ID NO:27), KICTCPGRD (SEQ ID NO:28), RVCTCPGRD (SEQ ID NO:29), KVCTCPGRD (SEQ ID NO:30), FXCKNSC (SEQ ID NO:31), and FXCQNSC (SEQ ID NO:32), wherein X is any amino acid.

7. (Amended) The isolated nucleic acid molecule of Claim [1] 4 wherein the [nucleic acid sequence encodes a] insect p53 polypeptide comprises an amino acid

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sequence selected from the group consisting of [having at least 50% sequence identity with] any of SEQ ID NOs 2, 4, 6, 8, and 10.

11. (Amended) A vector comprising the nucleic acid molecule of Claim [1] 4.

13. (Amended) A process for producing a p53 polypeptide comprising culturing the host cell of Claim [8] 12 under conditions suitable for expression of the p53 polypeptide and recovering the polypeptide.

Please cancel claims 1, 5, 6, 8-10, and 14-28.

Remarks

Claim 4 is amended to incorporate the features of canceled claims 8, 9, and 10, and to add Seq Id Nos. Claim 3 is amended to incorporate features described in the paragraph bridging pages 7-8 of the specification. Claim 7 is amended to be more concise. The remaining amendments are made to correct claim dependency. No new matter is introduced.

Response to Office Action

Elections/Restrictions

The election summarized in item 1 of the office action is confirmed.

Claim Rejections – 35 USC § 112

In item 2 of the office action, the Examiner rejected claims 3 and 7 under 35 U.S.C. § 112, first paragraph because of the recitation of “50% identity”. The amended claims no longer include this feature. It is believed that the amended claims satisfy the requirements of 35 USC § 112, 1st paragraph, and the rejection should be withdrawn.

In item 4 of the office action, the Examiner rejected Claim 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular,

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it was not clear to the Examiner how the amino acid sequences recited in the claim relate to SEQ ID NO:2.

Applicants were the first to discover the existence of p53 tumor suppressor genes in insects, and regard as their invention isolated nucleic acids that encode insect p53 polypeptides. Applicants discovered that insect p53 polypeptides have distinct structural differences that distinguish them from other known p53s. Specifically, insect p53s contain unique amino acid sequences within the DNA binding domain. These unique sequences are described on page 14, lines 1-16, and on page 17, lines 20-26, and are recited in claim 4. Seq Id Nos. for these sequences are provided in the amended claims and specification. An amended sequence listing is filed herewith.

It is believed that amended claim 4, in light of the disclosure on page 14, satisfies the requirements of 35 U.S.C. § 112, second paragraph, and that the rejection should be withdrawn.

Claim Rejections – 35 USC §§ 102 and 103

The Examiner rejected claims 1, 5, and 6 under 35 U.S.C. § 102(b) as anticipated by Harvey et al. (Genbank Accession Number A1516383). This reference discloses a 5' EST sequence having identity with nucleotides 67-716 of Seq Id No. 1. The present application claims priority to U.S. serial no. 09/268,969 filed March 16, 1999. Seq Id. No. 1 in the priority application is the same as Seq Id. No. 1 in the present application. The Harvey et al. sequence was entered in NCBI on March 16, 1999, as indicated in the printout of the NCBI entry attached as Appendix C (and as shown on Ref. U provided with the Office Action). This is the same date as applicant's priority filing date, and thus the Harvey et al. reference is not available as prior art under 35 U.S.C. § 102 (a) or (b), because it is not a publication before Applicants' invention. Accordingly, this rejection, and the rejection made under 35 U.S.C. §103(a) based on Harvey et al., should be withdrawn.

Conclusion

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It is believed that all of the rejections raised by the Examiner have been addressed and that the application is in condition for allowance. The Examiner is encouraged to telephone the undersigned with any questions regarding this response.

Respectfully submitted,


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Appendix A

2. (Amended) The isolated nucleic acid molecule of Claim 4 that is RNA.
3. (Amended) The isolated nucleic acid molecule of Claim 4 that hybridizes under stringent hybridization conditions with a nucleic acid having a sequence selected from the group consisting of any of SEQ ID NOs:1, 3, 5, 7, 9, 18, 19 and 21.
4. (Amended) An isolated nucleic acid molecule that encodes a polypeptide selected from the group consisting of an insect p53 polypeptide, a dominant negative form of said insect p53 polypeptide, a constitutively active form of said insect p53 polypeptide, and a domain of said insect p53 polypeptide selected from the group consisting of an activation domain, a DNA binding domain, a linker domain, an oligomerization domain, and a basic regulatory domain; wherein said insect p53 polypeptide comprises an amino acid sequence selected from the group consisting of: RICSCPGRD (SEQ ID NO:23), KICSCPGRD (SEQ ID NO:24), RVCSCPGRD (SEQ ID NO:25), KVCSCPGRD (SEQ ID NO:26), RICTCPGRD (SEQ ID NO:27), KICTCPGRD (SEQ ID NO:28), RVCTCPGRD (SEQ ID NO:29), KVCTCPGRD (SEQ ID NO:30), FXCKNSC (SEQ ID NO:31), and FXCQNSC (SEQ ID NO:32), wherein X is any amino acid.
7. (Amended) The isolated nucleic acid molecule of Claim 4 wherein the insect p53 polypeptide comprises an amino acid sequence selected from the group consisting of any of SEQ ID NOs 2, 4, 6, 8, and 10.
11. (Amended) A vector comprising the nucleic acid molecule of Claim 4.
12. A host cell comprising the vector of Claim 11.

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13. (Amended) A process for producing a p53 polypeptide comprising culturing the host cell of Claim 12 under conditions suitable for expression of the p53 polypeptide and recovering the polypeptide.

Appendix B

Other preferred p53 polypeptides, fragments or derivatives consist of or comprise a sequence selected from the group consisting of RICSCP_KRD (SEQ ID NO:23), KICSCP_KRD (SEQ ID NO:24), RVCSCP_KRD (SEQ ID NO:25), KVCSCP_KRD (SEQ ID NO:26), RICTCP_KRD (SEQ ID NO:27), KICTCP_KRD (SEQ ID NO:28), RVCTCP_KRD (SEQ ID NO:29), and KVCTCP_KRD (SEQ ID NO:30) (i.e. sequences of the formula: (R or K)(I or V)C(S or T)CP_KRD). Additional preferred p53 polypeptides, fragments or derivatives, consist of or comprise a sequence selected from the group consisting of FXCKNSC (SEQ ID NO:31) and FXCQNSC (SEQ ID NO:32), where X = any amino acid.